K122050

5 510(k) Summary

Submitter's Name and Address

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OCT 2 2 2012

Device Name

Proprietary Name:	CPRmeter™
Common Name:	CPR feedback device
Classification Name:	Cardiopulmonary Resuscitation Aid

Device Description

The CPRmeter™ device is small, lightweight (approximately the size and weight of a cell phone), and powered by a replaceable battery. The CPRmeter device is intended for use by responders who have been trained in CPR and use of the CPRmeter device. If in doubt about the appropriateness for use or ability to use, CPR is to be performed without using the CPRmeter device.

When attached to the bare chest of a suspected SCA victim, the CPRmeter device provides real-time feedback on CPR compressions in accordance with current CPR guidelines. It displays CPR feedback indicators for depth, rate, and release of chest compressions. It also counts the number of compressions in a series and provides notification of lack of expected CPR activity.

Indications for Use

The CPRmeter is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.

Predicate Devices

The legally marketed devices to which Laerdal Medical AS claims equivalence for the CPRmeter device are:

- Compression sensor of the HeartStart MRx Monitor/Defibrillator with Q-CPR® Option (Philips Medical Systems), K051134
- PocketCPR™ CPR feedback device (Bio-Detek, Incorporated), K071321

Data Used in Determination of Substantial Equivalence

Design verification and design validation testing demonstrates that the CPRmeter device meets its functional requirements and performance specifications. In particular,

- Biocompatibility testing on the patient-contacting materials of the CPRmeter device demonstrates an acceptable biocompatibility profile for the device,

- Testing in accordance with IEC60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety*, including Amendment 1 (1991) and Amendment 2 (1995), IEC 60601-1-2:2001, *General requirements for safety - Collateral standard: Electromagnetic compatibility - requirements and tests,* with Amendment 1:2004, and IEC 60601-1-4:2000, Consolidated Edition 1.1, *Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems*, demonstrates acceptable electromagnetic compatibility and electrical safety.

- Software testing demonstrates acceptable performance of the software.

- Compression depth detection and accuracy have been verified under a wide variety of use or pre-use conditions (e.g., drop testing, temperature and humidity stress, after repeated cleaning). That testing provides substantial evidence of the device's durability and its ability to perform acceptably under a wide variety of stresses, under the labeled shelf-life and operating conditions specified in the labeling.

Conclusion

Based on the results of the testing and other information submitted in the 510(k) application, the CPRmeter device does not raise any different questions regarding the safety or effectiveness compared to the predicate devices. Further, the device was tested based on accepted scientific methods and the performance data demonstrate substantial equivalence; therefore, the CPRmeter device is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Laerdal Medical AS
c/o Ms. Mari Kaada
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Re: K122050
CPRmeter™ CPR Feedback Device
Regulation Number: 21 CFR 870.5200
Regulation Name: Cardiopulmonary Resuscitation Aid
Regulatory Class: Class III
Product Code: LIX
Dated: July 6, 2012
Received: July 12, 2012

Dear Ms. Kaada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122050

Device Name: CPRMeter™ CPR Feedback Device

Indications For Use:

The CPRMeter is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.

Prescription Use _X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122050